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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,572	04/18/2005	Takashi Kenmoku	03500.017652.	2325
5514 7590 01/22/2009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER HANLEY, SUSAN MARIE				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,572

Applicant(s)

KENMOKU ET AL.

Examiner

SUSAN HANLEY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/08 has been entered.

Priority

Applicant has filed a certified translation of the foreign priority JP2002-309786 (filed 2/14/08) in its entirety. The translation discloses the polyhydroxyalkanoate monomer A, structure 26 at page 40. This monomer is identical to the monomer disclosed by the Yano prior art, formula 38 at page 27. Therefore, the disclosure of the certified translation supports the foreign priority claim and the priority of the instant application extends to 10/24/02.

Election/Restrictions

The lack of unity made on 10/9/07 was based on Yano et al. (EP 1,340,776; cited in the IDS filed 4/18/05) is withdrawn in light of the perfection of the foreign priority claim to JP 2002-309786. Hence, there is no lack of unity and all of the claims are rejoined.

Claims 21-37 are under examination.

Claim Rejections - 35 USC § 102

The rejection of claims 1 and 4 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by Yano et al. (EP 1,340,776; cited in the IDS filed 4/18/05) is withdrawn owing to the perfection of the foreign priority claim.

The rejection of claims 21 and 24 stand under 35 U.S.C. 102(e) as being anticipated by US 6,911,520, US 6,908,721, US 6,649,380 or US 6,645,743 is withdrawn owing to the perfection of the foreign priority claim.

Double Patenting

Claims 21 and 24 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,911,520.

Claims 21 and 24 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,908,721.

Applicant argues that the filing of a terminal disclaimer at this time is premature and expensive.

Applicant's argument is not directed to the factual basis of the rejection and is, therefore, non-persuasive. The rejections stand for the reasons of record.

Claims 21 and 24 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,645,743. This rejection was made in the Office action mailed 10/31/07 but was inadvertently left off of the Final office action. It is now reinstated.

Claims 21 and 24-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8 and 9 of U.S. Patent No. 6,649,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because are not patentably distinct from each other because claimed subject matter claimed in claims 21 and 24 of the instant application significantly overlap the scope of claims of the '380 patent : chemical structures of PHA copolymers claimed in both documents claim a monomer unit comprising a 3-hydroxy-w-[(phenylmethyl)oxy]alkanoate that corresponds to structure (1) of instant claim 21. This rejection was made in the Office action mailed 10/31/07. Claims 25-37 which are directed to the method of making the claimed polymers are now included in the rejection since the claims are now rejoined and the scope of the instant method claims overlaps the method claims of the patent.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 21-37 are drawn to polymers comprising the novel polyhydroxyalkanoate monomer of formula (1), copolymers thereof and methods

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for preparing the same. Claim 37 is drawn to a method of making said polymers employing microorganisms belonging to the strains *Pseudomonas cichorii* YN2 (FERM BP-7375), *Pseudomonas cichorii*, H45 (FERM BP-7374) and *Pseudomonas jessenii* P161 (FERM BP-7376).

Since said microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganisms of the said strains are not so obtainable or available, the requirements of 35 USC 112, first paragraph may be satisfied by a deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not apparent if the microorganisms are readily available to the public. The specification discloses that the strains were deposited under the Budapest Treaty were deposited on November 20, 2000 at the International Patent Organism Depositary (IPOD) of National Institute of Advanced Industrial Science and Technology (AIST), Tsukuba Central 6, I-I, Higashi I-chome, Tsukuba-shi, Ibaraki-ken 305-8566, Japan, and they are described in U.S. Patent 6,586,562.

However, neither the instant specification nor the record for U.S. Patent 6,586,562 define the conditions of availability of the deposited strains to the public upon issuance of a patent for said strains. Since the deposit is made under the terms of the Budapest Treaty, an affidavit or declaration by applicants, or a statement by an attorney of record over his or hers signature and registration number, **stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be**

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irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Claims 25-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of preparation of a polymer comprising the novel polyhydroxyalkanoate monomer of formula (1) and copolymers thereof by the fermentation of a monomer having the formula (19) and other polyhydroxyalkanoate monomers, as desired, with *Pseudomonas cichorii* YN2 (FERM BP-7375), *Pseudomonas cichorii*, H45 (FERM BP-7374) and *Pseudomonas jessenii* P161 (FERM BP-7376) under suitable conditions to make the desired polymers, does not reasonably provide enablement for said preparation of a polymer comprising the novel polyhydroxyalkanoate monomer of formula 1 and copolymers thereof by any possible chemical or biological method wherein the microorganisms belong to any possible species or strain including *Pseudomonas*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 25-35 are drawn to the preparation of a polymer comprising the novel polyhydroxyalkanoate monomer of formula (1) and copolymers thereof by culturing a monomer of formula (19) with possible microorganism with an ability to produce a polyhydroxyalkanoate expressed by formula (1). Claim 36 is drawn to the use of microorganisms belonging to the genus *Pseudomonas* and claim 37 limits the microorganisms to the strains *Pseudomonas cichorii* YN2 (FERM BP-7375),

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Pseudomonas cichorii, H45 (FERM BP-7374) and *Pseudomonas jessenii* P161 (FERM BP-7376). The specification shows that microorganisms belonging to the strains *Pseudomonas cichorii* YN2 (FERM BP-7375), *Pseudomonas cichorii*, H45 (FERM BP-7374) and *Pseudomonas jessenii* P161 (FERM BP-7376) are capable of performing the desired reaction to convert monomer (19) substrate to the polymer (1). The limited showing of three bacterial strains with a particular activity is not sufficient to enable a claim drawn to all species or strains of microorganisms.

The specification does not disclose if one skilled in the art can utilize any species or strain of microorganism including the genus of *Pseudomonas* to carry out the desired reaction of claim 1 with a reasonable expectation of results. Applicants point out that a number of PHA polymers have been synthesized. The specification teaches that "the inventors have found a method for synthesizing PHA comprising a unit having a highly reactive (phenylmethyl)oxy structure as an active group by using microorganisms" (p. 8). Thus, PHA polymers having the monomer of formula (1) were previously unknown and the only known synthesis is by biological means. The specification discloses only three species of microorganisms that can produce the desired PHA. There is no disclosure that provides the skilled artisan with guidance as to what identifying characteristics one would look for to identify a microorganism with the desired formula (1) producing properties. Hence, one skilled in the art would be unable to pick a species or strain from any possible type of microorganisms including the genus *Pseudomonas*, and expect it to possess the same set of properties necessary to produce PHA polymers comprising the monomer o formula (1). If the method of claims

21-36 are not generally applicable to any microorganism, then the desired activity all possible microorganisms including the genus *Pseudomonas* would be considered individually. This would be considered undue experimentation.

There is no reliable method that predicts which microorganisms have the desired activity to produce PHA polymers having the novel monomer of formula (1) and copolymers thereof as described in the specification. Applicants acknowledge that the monomer of formula (1) is novel and polymers thereof are presently made only by biological means. The specification does not teach how one of ordinary skill in the art could decide *a priori* which sources will provide a microorganism with the desired characteristics. The limited disclosure cannot be extrapolated by the skilled artisan to predict which microorganisms other than those disclosed by claim 37. It would require one of ordinary skill in the art undue experimentation to determine microorganisms other than those of claim 37 that can produce PHA polymers comprising the novel monomer of formula (1) and copolymers thereof according to the directions of the instant disclosure. Thus, claims 1-8 are not commensurate in scope with the enabling disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651